

## **EXHIBIT A**

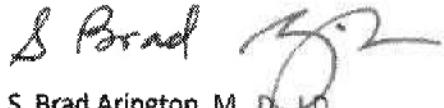
Denise Barbeau, Program Manager  
Arizona Department of Health Services  
Division of Public Health Services  
Office of Laboratory Licensing and Certification  
CLIA Certification Program Services  
250 N. 17<sup>th</sup> Avenue  
Phoenix, AZ 85007

October 24, 2016

Dear Ms. Barbeau:

Please be advised that Theranos, Inc. hereby relinquishes its CLIA Certificate number #03D2077896 for its laboratory located at North Scottsdale Rd., Scottsdale, AZ. We are confirming the closure of the lab and surrender of the CLIA certificate per our previous notification to CMS dated October 5, 2016, which was received and acknowledged by letter from CMS on October 12, 2016. The lab accepted the last patient samples on October 5, 2016 and ceased all testing of samples after the last shift of that same day. The last test report generated and issued by the lab was on October 13, 2016, as that report was pending results from a reference lab. We have included an executed CMS 116 for closure of the lab, indicating the date of that last report.

Best regards,



S. Brad Arlington, M. D., J.D.  
Chief Regulatory Counsel

Enclosures

cc: Donald Tschirhart, M.D., Laboratory Directory, Scottsdale, Arizona  
Elizabeth Holmes, Theranos CEO  
David Taylor, Theranos Acting General Counsel

Karen Fuller  
State Oversight and CLIA Branch  
Division of Survey and Certification  
Centers for Medicare & Medicaid Services  
Western Division of Survey & Certification  
San Francisco Regional Office  
90 7<sup>th</sup> Street, Suite 5-300 (5W)  
San Francisco, CA 94103-6707

# CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

## I. GENERAL INFORMATION

|   |   |  |   |  |                          |  |
|---|---|--|---|--|--------------------------|--|
| <input type="checkbox"/> Initial Application <input type="checkbox"/> Survey  | <b>CLIA IDENTIFICATION NUMBER</b><br>03 2077896<br><small>D</small> |  |   |  |                          |  |
| <input checked="" type="checkbox"/> Closure/Other Changes (Specify) <u>Closure</u>  |   |  |   |  |                          |  |
| Effective Date <u>October 13, 2016</u>  |   |  |   |  |                          |  |
| <b>FACILITY NAME</b><br>Theranos, Inc.  |   | <b>FEDE RA/TAX IDENTIFICATION NUMBER</b><br>20-1231826   |   |  |                          |  |
| <b>EMAIL ADDRESS</b><br>labsupport@theranos.com   |   | <b>TELEPHONE NO. (Include area code)</b> 650-838-9292 <b>FAX NO. (Include area code)</b> 650-838-9265                  |   |  |                          |  |
| <b>FACILITY ADDRESS — Physical Location of Laboratory (Building, Floor, Suite if applicable.) Fee Coupon/Certificate will be mailed to this Address unless mailing or corporate address is specified</b><br><b>NUMBER, STREET (No P.O. Boxes)</b><br>1365 N Scottsdale RD STE 350 |   |  |   |  |                          |  |
| <b>CITY</b><br>Scottsdale   | <b>STATE</b><br>AZ  | <b>ZIP CODE</b><br>85257   | <b>CITY</b><br>Palo Alto                          | <b>STATE</b><br>CA   | <b>ZIP CODE</b><br>94304 |  |
| <b>SEND CERTIFICATE TO THIS ADDRESS</b>   |   | <b>SEND FEE COUPON TO THIS ADDRESS</b>   |   | <b>CORPORATE ADDRESS (if different from facility) send Fee Coupon or certificate</b><br><b>NUMBER, STREET</b><br>1701 Page Mill Road |                          |  |
| <input type="checkbox"/> Physical<br><input type="checkbox"/> Mailing<br><input checked="" type="checkbox"/> Corporate  |   | <input type="checkbox"/> Physical<br><input type="checkbox"/> Mailing<br><input checked="" type="checkbox"/> Corporate |   |  |                          |  |
| <b>NAME OF DIRECTOR (Last, First, Middle Initial)</b><br>Donald Tschirhart, M.D.  |   |  | <b>CITY</b><br>Palo Alto                          | <b>STATE</b><br>CA   | <b>ZIP CODE</b><br>94304 |  |
| <b>CREDENTIALS</b>  |   |  | <b>FOR OFFICE USE ONLY</b><br>Date Received _____ |  |                          |  |

## II. TYPE OF CERTIFICATE REQUESTED ((Check only one) Please refer to the accompanying instructions for inspection and certificate testing requirements)

- Certificate of Waiver (Complete Sections I – VI and IX – X)
- Certificate for Provider Performed Microscopy Procedures (PPM) (Complete Sections I – X)
- Certificate of Compliance (Complete Sections I – X)
- Certificate of Accreditation (Complete Sections I – X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes.

|   |                               |                               |                               |
|---|-------------------------------|-------------------------------|-------------------------------|
| <input type="checkbox"/> The Joint Commission | <input type="checkbox"/> AOA  | <input type="checkbox"/> AABB | <input type="checkbox"/> A2LA |
| <input type="checkbox"/> CAP                  | <input type="checkbox"/> COLA | <input type="checkbox"/> ASHI |                               |

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

**NOTE:** Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Proof of these qualifications for the laboratory director must be submitted with this application.

**III. TYPE OF LABORATORY (Check the one most descriptive of facility type)**

|  |   |  |
|--|---|--|
| <input type="checkbox"/> 01 Ambulance                                      | <input type="checkbox"/> 13 Hospice   | <input type="checkbox"/> 22 Practitioner Other (Specify) _____         |
| <input type="checkbox"/> 02 Ambulatory Surgery Center                      | <input type="checkbox"/> 14 Hospital  | <input type="checkbox"/> 23 Prison                                     |
| <input type="checkbox"/> 03 Ancillary Testing Site in Health Care Facility | <input type="checkbox"/> 15 Independent   | <input type="checkbox"/> 24 Public Health Laboratories                 |
| <input type="checkbox"/> 04 Assisted Living Facility                       | <input type="checkbox"/> 16 Industrial  | <input type="checkbox"/> 25 Rural Health Clinic                        |
| <input type="checkbox"/> 05 Blood Bank                                     | <input type="checkbox"/> 17 Insurance   | <input type="checkbox"/> 26 School/Student Health Service              |
| <input type="checkbox"/> 06 Community Clinic                               | <input type="checkbox"/> 18 Intermediate Care Facilities for Individuals with Intellectual Disabilities | <input type="checkbox"/> 27 Skilled Nursing Facility/ Nursing Facility |
| <input type="checkbox"/> 07 Comp. Outpatient Rehab Facility                | <input type="checkbox"/> 19 Mobile Laboratory   | <input type="checkbox"/> 28 Tissue Bank/Repositories                   |
| <input type="checkbox"/> 08 End Stage Renal Disease Dialysis Facility      | <input type="checkbox"/> 20 Pharmacy  | <input type="checkbox"/> 29 Other (Specify) _____                      |
| <input type="checkbox"/> 09 Federally Qualified Health Center              | <input type="checkbox"/> 21 Physician Office  |  |
| <input type="checkbox"/> 10 Health Fair                                    | Is this a shared lab?   |  |
| <input type="checkbox"/> 11 Health Main. Organization                      | <input type="checkbox"/> Yes <input type="checkbox"/> No  |  |
| <input type="checkbox"/> 12 Home Health Agency                             |   |  |

**IV. HOURS OF LABORATORY TESTING (List times during which laboratory testing is performed in HH:MM format) If testing 24/7 Check Here** 

|       | SUNDAY | MONDAY | TUESDAY | WEDNESDAY | THURSDAY | FRIDAY | SATURDAY |
|-------|--------|--------|---------|-----------|----------|--------|----------|
| FROM: |        |        |         |           |          |        |          |
| TO:   |        |        |         |           |          |        |          |

(For multiple sites, attach the additional information using the same format.)

**V. MULTIPLE SITES (must meet one of the regulatory exceptions to apply for this provision in 1-3 below)**

Are you applying for a single site CLIA certificate to cover multiple testing locations?

 No. If no, go to section VI.  Yes. If yes, complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

1. Is this a laboratory that is not at a fixed location, that is, a laboratory that moves from testing site to testing site, such as mobile unit providing laboratory testing, health screening fairs, or other temporary testing locations, and may be covered under the certificate of the designated primary site or home base, using its address?

 Yes  No

If yes and a mobile unit is providing the laboratory testing, record the vehicle identification number(s) (VINs) and attach to the application.

2. Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?

 Yes  No

If yes, provide the number of sites under the certificate \_\_\_\_\_ and list name, address and test performed for each site below.

3. Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?

 Yes  No

If yes, provide the number of sites under this certificate \_\_\_\_\_ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here  and attach the additional information using the same format.

| NAME AND ADDRESS/LOCATION                                 | TESTS PERFORMED/SPECIALTY/SUBSPECIALTY |
|---|--|
| NAME OF LABORATORY OR HOSPITAL DEPARTMENT                 |  |
| ADDRESS/LOCATION (Number, Street, Location if applicable) |  |
| CITY, STATE, ZIP CODE                                     | TELEPHONE NO. (Include area code)      |
| NAME OF LABORATORY OR HOSPITAL DEPARTMENT                 |  |
| ADDRESS/LOCATION (Number, Street, Location if applicable) |  |
| CITY, STATE, ZIP CODE                                     | TELEPHONE NO. (Include area code)      |

In the next three sections, indicate testing performed and annual test volume.

#### VI. WAIVED TESTING

Identify the waived testing (to be) performed. Be as specific as possible. This includes each analyte test system or device used in the laboratory.

e.g. (Rapid Strep, Acme Home Glucose Meter)

N/A -- Closure

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all waived tests performed \_\_\_\_\_

Check if no waived tests are performed

#### VII. PPM TESTING

Identify the PPM testing (to be) performed. Be as specific as possible.

e.g. (Potassium Hydroxide (KOH) Preps, Urine Sediment Examinations)

N/A

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all PPM tests performed \_\_\_\_\_

For laboratories applying for certificate of compliance or certificate of accreditation, also include PPM test volume in the specialty/subspecialty category and the "total estimated annual test volume" in section VIII.

Check if no PPM tests are performed

If additional space is needed, check here  and attach additional information using the same format.

#### VIII. NON-WAIVED TESTING (Including PPM testing if applying for a Certificate of Compliance or Accreditation)

If you perform testing other than or in addition to waived tests, complete the information below. If applying for one certificate for multiple sites, the total volume should include testing for ALL sites.

Place a check (✓) in the box preceding each specialty/subspecialty in which the laboratory performs testing. Enter the estimated annual test volume for each specialty. Do not include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. (For additional guidance on counting test volume, see the instructions included with the application package.)

If applying for a Certificate of Accreditation, indicate the name of the Accreditation Organization beside the applicable specialty/subspecialty for which you are accredited for CLIA compliance. (The Joint Commission, AOA, AABB, CAP, COLA or ASHI)

| SPECIALTY /<br>SUBSPECIALTY                     | ACCREDITING<br>ORGANIZATION | ANNUAL<br>TEST VOLUME | SPECIALTY /<br>SUBSPECIALTY                                      | ACCREDITING<br>ORGANIZATION | ANNUAL<br>TEST<br>VOLUME |
|---|-----------------------------|-----------------------|--|-----------------------------|--------------------------|
| HISTOCOMPATIBILITY 010                          |                             |                       | HEMATOLOGY 400   |                             |                          |
| <input type="checkbox"/> Transplant             |                             |                       | <input type="checkbox"/> Hematology                              |                             |                          |
| <input type="checkbox"/> Nontransplant          |                             |                       | IMMUNOHEMATOLOGY   |                             |                          |
| MICROBIOLOGY                                    |                             |                       | <input type="checkbox"/> ABO Group & RhGroup 510                 |                             |                          |
| <input type="checkbox"/> Bacteriology 110       |                             |                       | <input type="checkbox"/> Antibody Detection (transfusion) 520    |                             |                          |
| <input type="checkbox"/> Mycobacteriology 115   |                             |                       | <input type="checkbox"/> Antibody Detection (nontransfusion) 530 |                             |                          |
| <input type="checkbox"/> Mycology 120           |                             |                       | <input type="checkbox"/> Antibody Identification 540             |                             |                          |
| <input type="checkbox"/> Parasitology 130       |                             |                       | <input type="checkbox"/> Compatibility Testing 550               |                             |                          |
| <input type="checkbox"/> Virology 140           |                             |                       | PATHOLOGY  |                             |                          |
| DIAGNOSTIC IMMUNOLOGY                           |                             |                       | <input type="checkbox"/> Histopathology 610                      |                             |                          |
| <input type="checkbox"/> Syphilis Serology 210  |                             |                       | <input type="checkbox"/> Oral Pathology 620                      |                             |                          |
| <input type="checkbox"/> General Immunology 220 |                             |                       | <input type="checkbox"/> Cytology 630                            |                             |                          |
| CHEMISTRY                                       |                             |                       | RADIOBIOASSAY 800  |                             |                          |
| <input type="checkbox"/> Routine 310            |                             |                       | <input type="checkbox"/> Radiobioassay                           |                             |                          |
| <input type="checkbox"/> Urinalysis 320         |                             |                       | CLINICAL CYTOGENETICS 900  |                             |                          |
| <input type="checkbox"/> Endocrinology 330      |                             |                       | <input type="checkbox"/> Clinical Cytogenetics                   |                             |                          |
| <input type="checkbox"/> Toxicology 340         |                             |                       | <b>TOTAL ESTIMATED ANNUAL TEST VOLUME:</b>                       | N/A                         |                          |

**IX. TYPE OF CONTROL (check the one most descriptive of ownership type)****VOLUNTARY NONPROFIT**

01 Religious Affiliation  
 02 Private Nonprofit  
 03 Other Nonprofit

(Specify)

**FOR PROFIT**

04 Proprietary

**GOVERNMENT**

05 City  
 06 County  
 07 State  
 08 Federal  
 09 Other Government

(Specify)

**X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES**

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

| CLIA NUMBER | NAME OF LABORATORY |
|-------------|--------------------|
| None        |                    |
|             |                    |
|             |                    |
|             |                    |
|             |                    |
|             |                    |

**ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION**

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

**Consent:** The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

**SIGNATURE OF OWNER/DIRECTOR OF LABORATORY (Sign in Ink)****DATE**

October 24, 2016

**NOTE: Completed 116 applications must be sent to your local State Agency.****SEE ATTACHED LIST OF STATE AGENCY CONTACT INFORMATION.**<http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf>

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0581. The time required to complete this information collection is estimated to average 30 minutes to 2 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, Attn: PRA Reports Clearance Officer, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.